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EXAMINER	
SIMS, JASON M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,063	MARLOWE ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/30/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 9/30/2009, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 9/30/2009, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant has newly added claims 26 and 27 in the response filed 9/30/2009, which have been acknowledged and entered.

Applicant has cancelled claims 22-25 in the response filed 9/30/2009, which has been acknowledged.

Claims 14-21 and 26-27 are the current claims hereby under examination.

Claim Rejections - 35 USC § 103-Modified

Response to Arguments

Applicant's arguments with respect to claims 16-21 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (US P/N 5,968,731) in view of Brown-Augsburger et al. (US P/N 2002/0137060).

With regards to limitations of claims 14-15: Layne et al. teach a system comprising process control tools (PCTs, which interface remote clients and the automated testing instruments), infectrons, and detectrons (where the infectrons and detectrons each is comprised of a group of interchangeable standard laboratory modules (SLMs) and standard support modules (SSMs) that perform the automated testing.) Layne et al. at col. 8, lines 15-30 teach that a remote client interfaced with a PCT is used to give a user/researcher access to the automated lab, wherein the user/research can define and perform the automated tests and to design experiments to be performed (lines 29-30). Layne et al. further teach at col. 8, lines 34-37 that the automated instruments perform the tests specified by the remote user. Thus Layne et al. teach receiving a binding assay design for a binding assay. Further, Layne et al. teach generating binding-ready biological sample (see col. 8, lines 24-26). In addition, Layne et al. teach that if the desired tests require submission of test specimens, the

program control tools are used to define the requirements for packaging and labeling these specimens. As such, Layne et al. refer to the SLMs and SSMs that prepare the assay as the infectron. Furthermore, Layne et al. at col. 12, lines 37-67 discuss components of the infectron, i.e. the viral cell inoculation SLM, incubation SLM, and cell washing SLM, which prepare the binding-ready biological sample. Layne et al. at col. 12, lines 37-67 further discuss a microtiter plate preparation SLM component that prepares the plate for the binding assay. Therefore the infectron and detectron, which act on instructions provided by the process controller, and indirectly a remote client user/researcher, read on the step of preparing an experiment design for generating a binding-ready biological sample to be used in said binding assay. Furthermore, the sample is considered a binding-ready biological sample because Layne et al. at col. 13, lines 21-24 teach that the sample prepared by the infectron will be used in an "enzyme-linked immuno-sorbent assay (ELISA)," which is a form of a binding assay. Layne et al. teach at col. 15, lines 5-15 that a remote client, wherein a user or researcher controls, may have a direct communication to the test instrument suite or may share information and instructions with the process controller. Layne et al. further teach at col. 15, lines 25-45 that the process controller receives test procedures defined by the remote client wherein the commands are then transformed into automated test suite commands, which define how the SSMs and SLMs, i.e. infectrons and detectrons, carry out their tasks, wherein the transformed designs into SLM commands reads on the step of generating work instructions for generating said binding-ready biological sample based on said experiment design and said robot method; and executing said work instructions

on robot stations to generate the binding-ready biological sample. Layne et al. at col. 14, lines 50-53 teach that the infectrons and detectrons contain standard laboratory modules that are removable and interchangeable, permitting easier maintenance and design improvements. Layne et al. teach at col. 12, lines 25-30 and col. 14, lines 33-35 examples of robots used as a component of the infectrons and detectrons, wherein the ability for selection of a particular module, i.e. robot, reads on the step of choosing a robot method for generating said binding-ready biological sample..

Layne et al. at col. 8, lines 28-30 teach that a user designs the experiments that are to be performed by the automated tester. Layne et al. at col.10, lines 33-43 teach that the system "allows researchers to design new experiments and offers the test designer specified degrees of freedom," which reads on the step of preparing an experiment design for generating a binding-ready biological sample to be used in said binding assay. Layne et al. at col. 11, lines 53-54 refer to a group of SLMs and SSMs an infectron, which carries out the automated testing.

Layne et al. at col. 9, lines 47-49 and lines 55-59 teach that the controllers of the automated testing optimize the sequences by which all tasks take place and are capable of dynamic retasking, which further enables optimization of performing experiments, thus anticipating claim 15.

Layne et al. do not explicitly teach a binding assay that is a hybridization assay where the sample is a nucleic acid sample.

Brown-Augsburger et al. at Figs 1-3, paragraphs [0140] – [0141], and [0192] and throughout the application performing an ELISA-hybridization assay where the sample is a nucleic acid sample.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the apparatus for performing automated testing of biological specimens as taught by Layne et al. for use in performing ELISA-hybridization assays where the sample is a nucleic acid sample as taught by Brown-Augsburger et al. This is because Layne et al. teach an apparatus, which is programmable, for automatically performing ELISA assays. Layne et al. further teach in the Background section that automated laboratory instruments and the use of standard laboratory modules are well known and their use is recognized as part of the ordinary skill of one in the art. Therefore, using an automated apparatus that is programmable to perform the automated testing of biological specimens, such as performing an ELISA binding assay, was recognized as part of the ordinary capabilities of one skilled in the art. Furthermore, Layne et al. teach that the "PCTs would be provided in platform independent instructions taking advantage of object oriented programming and modular techniques to allow support of practically any SLM instrument and to interface with a wide variety of remote client 100 access platforms," thus anticipating many different types of modifications (see col. 11, lines 21-46). In addition, Layne et al. teach at col. 6, lines 33-44 that the apparatus allows researchers to design new experiments. One of ordinary skill in the art would have been capable of applying this known technique to a known method as taught by Brown-Augsburger, wherein the modification of said

automation would be an obvious variant, and the results would have been predictable to one of ordinary skill in the art.

The following rejection is being newly applied, which was necessitated by amendment:

Claims 16-21 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (US P/N 5,968,731) in view of Brown-Augsburger (US P/N 2002/0137060) as applied to claims 14-15 above and further in view of the following.

Layne et al. and Brown-Augsburger teach claims 14-15 as described above.

Layne et al. and Brown-Augsburger suggest, but do not explicitly teach a step of, before said generating, checking inventory for materials required for said experiment design.

Layne et al. suggest this because at col. 11, lines 22-26 and lines 58-59 they discuss a commerce PCT that interfaces with the SLMs, which implements functions related to "inventory management of test and support materials" and that materials for the automated testing may be obtained from the testing suite stock supplies. Therefore, it is implied that before obtaining the materials from the suite stock supplies, that inventory of those supplies would have been checked.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to have a system which performs automated testing based on user designs where the supplies may be obtained from the testing suite stock supplies as taught by Layne et al., but first performs a check for inventory of materials required for

said experiment. This is because an automated system capable of said functionality as taught by Layne et al. would need to be able to notify the remote client/user that inventory was not available or the automated system it depended on for obtaining materials would fail. Therefore, the differences between the claimed invention and the prior art were encompassed in known variation or in a principal known. In addition, the differences are the product not of innovation, but of ordinary skill in the art and common sense.

Layne et al. suggest, but do not explicitly teach the limitations of claims 17-19 wherein the claims are drawn to further limitations of checking inventory by sending a inventory request to an inventory system, receiving inventory data indicating whether said materials are available in inventory, and ascertaining from said inventory data whether said materials are available in inventory.

Layne et al. suggest this because at col. 11, lines 22-26 and lines 58-59 they discuss a commerce PCT that interfaces with the SLMs, which implements functions related to "inventory management of test and support materials" and that materials for the automated testing may be obtained from the testing suite stock supplies. Therefore, it is implied that before obtaining the materials from the suite stock supplies that inventory of those supplies would have been checked. Furthermore, Layne et al. teach an automated testing system, which performs the functions commanded by a user/researcher wherein the user/researcher is interfaced with the system via electronic communications. Therefore, it is further implied that an automated system would have

set up communication functions to alert the user/researcher with updates throughout the procedure.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have a system which performs automated testing based on user designs where the supplies may be obtained from the testing suite stock supplies as taught by Layne et al., but first performs a check for inventory of materials by performing the limitations of claims 17-19, such as sending a inventory request to an inventory system. This is because an automated system capable of said functionality as taught by Layne et al. would want to be able to notify the remote client/user that inventory was not available or the automated system, if depended on for obtaining materials, would fail. Therefore, the differences between the claimed invention and the prior art are the product not of innovation, but of ordinary skill in the art and common sense.

Layne et al. suggest, but do not explicitly teach wherein said receiving further comprises acquiring a tissue sample.

Layne et al. suggest this because at col. 8, lines 30-32 that "if required, specimens are then packaged and physically transported to the automated lab site." Layne et al. further teach at col. 11, lines 47-50 that the automated instrument suite for performing the testing, can test biological samples, which comprises cells. Layne et al. further teach at col. 12 and 13 the testing instrument suite prepares the assay, which included preparing the sample.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have acquired a tissue sample wherein cells could have been

extracted and prepared for the assay testing as taught by Layne et al. This is because the system taught by Layne et al. is directed to testing cell samples, which are often derived from tissue. Therefore, acquiring a tissue sample, from which a researcher will extract cells for performing an assay is the product not of innovation but of ordinary skill and common sense.

Layne et al. suggest, but do not explicitly teach the steps of extracting a constituent sample from said tissue sample; and updating inventory to include constituent sample as in claim 21.

Layne et al. suggest this because at col. 11, lines 66-67 and col. 12, lines 1-5 they teach that the infectron performs a number of operations including providing supply materials, pipetting, and storing samples wherein pipetting involves extracting a constituent sample from a biological sample and storing samples implies some type of registration or updating for the automated testing system.

It would have been obvious at the time of the instant invention to have extracted a constituent sample from a tissue sample and updated inventory to include said constituent sample in the automated testing system taught by Layne et al. This is because Layne et al. teach that the system is set up to extract constituent samples and store inventory and supply inventory. Therefore to include a process that updates the inventory to include the constituent sample is a product not of innovation, but of ordinary skill and common sense. Moreover, Layne et al. teaching a system that extracts constituent samples and further teach that the different SLMs and SSMs are interchangeable to improve experimental design is implicitly capable of extracting

constituent samples from a tissue sample with few interchangeable modifications. The differences between the claimed invention and prior art were encompassed in known variations as taught or in a principal known in the art as discussed.

Layne et al. and Brown-Augsburger et al. do not explicitly teach wherein said method further comprises a step of scheduling and executing step, said scheduling taking into account the relative priorities of experiments and availability of parts in inventory as in claim 27.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have modified the integrated SLM technology that provides a broad range of services to the scientific community as taught by Layn et al. and Brown-Augsburger et al. to have comprised a step of scheduling and executing step, said scheduling taking into account the relative priorities of experiments and availability of parts in inventory. This is because Layne et al. teach that the invention "implements functions related to the business aspects of the automated test facility, including billing, inventory management of test and support materials, cost modeling" etc. Furthermore, Layne et al. teach that the "PCTs would be provided in platform independent instructions taking advantage of object oriented programming and modular techniques to allow support of practically any SLM instrument and to interface with a wide variety of remote client 100 access platforms," thus anticipating many different types of modifications (see col. 11, lines 21-46). In addition, Layne et al. teach at col. 9, lines 10-19, that the SLMs have knowledge of the availability of the SSMs and "knows" whether there are enough materials for it to function and either proceed or report that it

cannot do so. Therefore, because the invention as taught by Layne et al. take into account the availability of parts in inventory and implement functions related to the business aspects such as cost modeling, it would have been further obvious to have modified the SLMs to take into account relative priorities of experiments. The relative priorities of experiments would be considered a business aspect to account for in the automated testing facility to an ordinary artisan. Therefore, one of ordinary skill in the art would have been capable of applying this known technique to the know device and the results would have been predictable.

The following rejection is being newly applied, which was necessitated by amendment:

Claim 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (US P/N 5,968,731) in view of Brown-Augsburger (US P/N 2002/0137060) as applied to claims 14-15 above and further in view of the following and further in view of Warrington et al. (US A/N 2003/0124539).

Layne et al. and Brown-Augsburger teach claims 14-15 as described above.

Layne et al. and Brown-Augsburger et al. do not explicitly teach wherein said work instructions comprise instructions for pooling a plurality of binding-ready biological samples each of which is a nucleic acid as in claim 26.

Warrington et al. teach an automated system for performing hybridization assays, wherein sample preparation comprises pooling (see paragraphs [0095] – [0105]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have modified the SLM system taught by Layne et al. and Brown-Augsburger et al. to comprise instructions for pooling a plurality of binding-ready biological samples as in the method taught by Warrington et al. This is because pooling is a particular known technique that is routine and recognized as part of the ordinary capabilities of one skilled in the art, which is taught by Warrington et al. Warrington et al. teach an automated system for performing hybridization assays, wherein sample preparation comprises pooling (see paragraphs [0095] – [0105]). Layne et al. teach that the "PCTs would be provided in platform independent instructions taking advantage of object oriented programming and modular techniques to allow support of practically any SLM instrument and to interface with a wide variety of remote client 100 access platforms," thus anticipating many different types of modifications (see col. 11, lines 21-46). In addition, Layne et al. teach at col. 6, lines 33-44 that the apparatus allows researchers to design new experiments, wherein it would have been routine to have anticipated the modification of an experiment to have included pooling. One of ordinary skill in the art would have been capable of applying this known technique to the taught device and the results would have been predictable to one of ordinary skill in the art.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /

/Marjorie Moran/
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